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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,766	03/24/2004	Benjamin Oshlack	305158-999007 CON9	7929
20583	7590	07/12/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 07/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/809,766

Applicant(s)

OSHLACK ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/14/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al (US 4,990,341).

Goldie et al '341 teach a method of making a controlled release composition for pra; delivery of hydromorphone comprising mixing the active agent with an hydroxyalkyl cellulose and a methacrylic acid copolymer, forming granules and drying at 50 degrees C. The granules are mixed with an aliphatic acohol, regranulated and compressed into tablets (title, example 3 column 6). Dosage forms containing 2-50 mg are disclosed (column 2 line 45). Treatment of pain is specified (column 1 lines 7-9). Delivery over over a 12 hour period is disclosed (column 3 lines 14-15).

It would have been obvious to one of ordinary skill to use the method of Goldie et al '341 to make a composition comprising oxycodone to achieve the beneficial effect of a controlled release vehicle in view of the structural similarity of hydromorphone and oxycodone, both of which are members of the morphine family of compounds.

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al (US 4,844,909).

Goldie et al '909 teach a method of making a controlled release composition for the oral delivery of hydrophorphone comprising making spheroids from microcrystalline

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cellulose, a polymethacrylate and a hydroxyalkyl cellulose, followed by coating (title, column 3 line 64-column 4 line 35).

It would have been obvious to one of ordinary skill to use the method of Goldie et al '909 to make a composition comprising oxycodone to achieve the beneficial effect of a controlled release vehicle in view of the structural similarity of hydromorphone and oxycodone, both of which are members of the morphine family of compounds.

Claims 2, 10, 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fatty alcohols, does not reasonably provide enablement for any aliphatic alcohol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 10 lines 11-26, 30-33 fatty alcohols are disclosed. Nowhere are short-chain alcohols specified.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500